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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.  | CONFIRMATION NO. |
|---|-------------|----------------------|----------------------|------------------|
| 09/375,514  | 08/17/1999  | JOHN C. REED         | 04040/1200990-US5    | 5198             |
| 7278  | 7590        | 05/17/2005           | EXAMINER             |                  |
| DARBY & DARBY P.C.<br>P. O. BOX 5257<br>NEW YORK, NY 10150-5257 |             |                      | VIVLEMORE, TRACY ANN |                  |
|   |             |                      | ART UNIT             | PAPER NUMBER     |

1635

DATE MAILED: 05/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 09/375,514             | REED, JOHN C.       |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Tracy Vivlemore        | 1635                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 53,70 and 72-88 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 53 and 76-81 is/are allowed.
- 6) ☒ Claim(s) 70,72-75 and 82 is/are rejected.
- 7) ☒ Claim(s) 83-88 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Priority***

Applicant's amendments to the claims have overcome the rejections of record under 35 USC 102 against claims 70 and 74. These claims are now supported by the disclosure of application 07/288,692 and have a priority date of December 12, 1988.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 70 and 72-74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Claims 70 and 72-74 have been amended to recite that the anticodon oligomer is complementary to a portion of a human bcl-2 mRNA or a portion of a human bcl-2 primary transcript. Each of these limitations finds literal support in the disclosure of application 07/288,692. The presence of the phrase "primary transcript" in the claim indicates that "human bcl-2 mRNA" refers to something other than the primary transcript. If this is the case, if for example it is meant to refer to an mRNA that has

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undergone processing to remove introns, this does not find clear support in the '692 application, which refers throughout the disclosure solely to "mRNAs" and in fact teaches away from "mature" mRNAs, see for example the '692 application on page 5, which contemplates anticodon oligomers are complementary to a splice donor or splice acceptor site; features not present in "mature" mRNAs (as evidenced by the instant specification that refers to targeting the splice donor site of bcl-2 "pre-mRNA"). Inserting the more generic term "mRNA" would be remedial.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 70, 72, 73, 75 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14, 16 and 18 of U.S. Patent No. 6,841,541. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims encompass the full scope of the claims of the '541 patent. The instant claims are directed to anticodon oligomers 10-40 bases in length that are complementary to a portion of a human bcl-2 mRNA including a splice donor or splice acceptor sites and compositions of these oligomers in a pharmaceutically acceptable carrier. The claims of the '541 patent are directed to compositions of anticodon oligomers 10-40 bases in length that are complementary to the mRNA, including the splice donor and splice acceptor sites, of SEQ ID NO: 19. This sequence is disclosed as being a human bcl-2 mRNA, meaning the scope of the patented claims is fully encompassed by the scope of the instant claims.

2. Claims 70, 73 and 82 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 5 of U.S. Patent No. 5,734,033. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims encompass the full scope of the claims of the '033 patent. The instant claims are directed to anticodon oligomers including phosphorothioates, 10-40 bases in length that are complementary to a portion

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of a human bcl-2 mRNA or the splice donor site of a bcl-2 mRNA. The claims of the '033 patent are directed to oligomers 10-35 bases in length that are complementary to a bcl-2 mRNA designated as SEQ ID NO: 2. This sequence is disclosed in table 1 as being a splice donor site of human bcl-2 mRNA, meaning the scope of the patented claims is fully encompassed by the scope of the instant claims.

### ***Allowable Subject Matter***

3. Claims 53 and 76-81 are allowed.
4. Claims 83-88 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Conclusion***

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:45-5:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It


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also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Tracy Vivlemore  
Examiner  
Art Unit 1635

TV  
May 10, 2005



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